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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,623	10/31/2001	Ahmed S. Mehanna	M0966/7001	5765

7590

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EXAMINER

JONES, DWAYNE C

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 03/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/998,623

Applicant(s)

MEHANNA ET AL.

Examiner

Dwayne C Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Preliminary Amendment of 31 OCT 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21 and 23-26 is/are allowed.
- 6) ☒ Claim(s) 20,22,27,35,36,38,40,42 and 44-54 is/are rejected.
- 7) ☐ Claim(s) 28-34, 37, 39, 41 and 43 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 20-54 are pending.
2. Claims 1-19 are cancelled as per Preliminary Amendment of October 31, 2001.
3. Claims 20, 22, 27, 35, 36, 38, 40, 42 and 44-54 are rejected.
4. Claims 28-34, 37, 39, 41 and 43 are objected to.
5. Claims 21, 23-25 and 26 are free of the prior art of record.

Claim Objections

6. Claims 28-34, 37, 39, 41 and 43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 27 and 44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the cardiovascular diseases of hypertension, congestive heart failure, arrhythmia and angina, pulmonary hypertension, peripheral vascular disorder, mania, epilepsy, depression, hyperuricemia and asthma, does not reasonably provide enablement for other types of disorders associated with calcium

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channel activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The instant specification only provides support for the following disorders that are associated with calcium channel activity, which are the cardiovascular diseases of hypertension, congestive heart failure, arrhythmia and angina, pulmonary hypertension, peripheral vascular disorder, mania, epilepsy, depression, hyperuricemia and asthma. There is no support or guidance for other types of disorders that are associated with calcium channel activity. In the absence further guidance, one skilled in the art is faced with an undue burden of experimentation in order to determine what are other types of disorders associated with calcium channel activity.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 22 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim must be in one sentence form only.

11. Claims 35, 36, 38, 40, 42 and 50-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. Claims 35, 36, 38, 40, 42 and 50-54 provide for the use of the compounds of general formula I, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass.

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A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

13. Claims 35, 36, 38, 40, 42 and 50-54 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. Claims 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gialdi et al. in view of McMurry. Gialdi et al. teach of compounds which resemble the instantly claimed compounds with two phenyl rings linked together with a methylthio moiety. The difference between the prior art reference of Gialdi et al. and the instant invention is that instant invention has an ortho carboxylic acid halide moiety whereas Gialdi et al. have a carboxylic acid amide moiety in the very same position. It is well established in the art

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that carboxylic acid derivatives can easily be converted into other carboxylic acid derivatives. In fact, McMurry teaches of the reactivities of carboxylic acid derivatives, see pages 742-746. McMurry discloses that an acid chloride is more reactive than a carboxylic acid amide due to electron withdrawing effects of the chlorine atom attached next to the acyl group, whereas the amino group donates electrons to the acyl group. Although McMurry states that amides cannot be converted into acid halides, McMurry does provide motivation to have a more reactive carboxylic acid derivative group, specifically an acyl chloride, in order to make other types of carboxylic acid derivatives, including less reactive carboxylic acid amides. Clearly, it would have been obvious to one having ordinary skill in the art to utilize the teachings of McMurry and replace a less reactive carboxylic acid derivative as the carboxylic acid amide of Gialdi et al. with a more reactive carboxylic acid derivative such as the instantly disclosed carboxylic acid chloride compound, especially in the organic synthesis of other compounds which are less reactive derivatives of the highly reactive carboxylic acid chloride.

16. Claims 44-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gialdi et al. Gialdi et al. teach of compounds which resemble the instantly claimed compounds with two phenyl rings linked together with a methylthio moiety. The difference between the prior art reference of Gialdi et al. and the instant invention is that instant invention has an ortho carboxylic acid halide moiety whereas Gialdi et al. have a carboxylic acid amide moiety in the very same position. Applicants attempt to limit claims 44-54 with the incorporation of an intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed

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invention and the prior art in order to patentably distinguish the claimed invention and the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See In re Casey, 152 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963).

17. Claims 44-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gialdi et al. in view of McMurry. Gialdi et al. teach of compounds which resemble the instantly claimed compounds with two phenyl rings linked together with a methylthio moiety. The difference between the prior art reference of Gialdi et al. and the instant invention is that instant invention has an ortho carboxylic acid halide moiety whereas Gialdi et al. have a carboxylic acid amide moiety in the very same position. It is well established in the art that carboxylic acid derivatives can easily be converted into other carboxylic acid derivatives. In fact, McMurry teaches of the reactivities of carboxylic acid derivatives, see pages 742-746. McMurry discloses that an acid chloride is more reactive than a carboxylic acid amide due to electron withdrawing effects of the chlorine atom attached next to the acyl group, whereas the amino group donates electrons to the acyl group. Although Hart states that amides cannot be converted into acid halides, McMurry do provide motivation to have a more reactive carboxylic acid derivative group, specifically an acyl chloride, in order to make other types of carboxylic acid derivatives, including less reactive carboxylic acid amides. Clearly, it would have been obvious to one having ordinary skill in the art to utilize the teachings of McMurry and replace a less reactive carboxylic acid derivative as the carboxylic acid amide of Gialdi et al. with a

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more reactive carboxylic acid derivative such as the instantly disclosed carboxylic acid chloride compound, especially in the organic synthesis of other compounds which are less reactive derivatives of the highly reactive carboxylic acid chloride. Moreover, the selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945).

Subject Matter Free of the Prior art

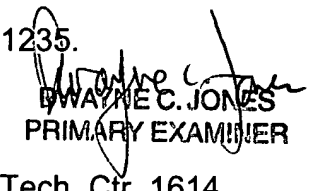
18. Claims 21, 23-25 and 26 are free of the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1235.


WAYNE C. JONES
PRIMARY EXAMINER

Tech. Ctr. 1614
March 7, 2002